

UNITED STATES DISTRICT COURT  
SOUTHERN DISTRICT OF NEW YORK

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In re ELAN CORPORATION SECURITIES LITIGATION : X Master File No. 1:08-cv-08761-AKH  
: CLASS ACTION

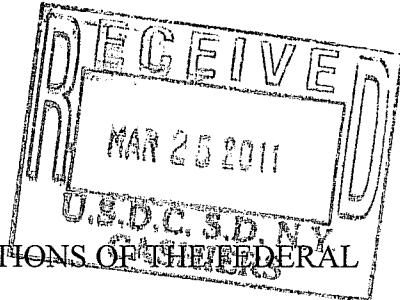
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This Document Relates To:

ALL ACTIONS.

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AMENDED CONSOLIDATED COMPLAINT FOR VIOLATIONS OF THE FEDERAL SECURITIES LAWS



## **INTRODUCTION AND OVERVIEW**

1. This is a class action for violations of the anti-fraud provisions of the federal securities laws on behalf of all purchasers of Elan Corporation, plc (“Elan” or the “Company”) American Depository Receipts (“ADRs”) listed and trading on the New York Stock Exchange (“NYSE”) between May 21, 2007 and October 21, 2008 (the “Class Period”).

2. Elan is a neuroscience-based biotechnology company. During the Class Period, Elan’s biggest-selling drug was Tysabri, a treatment for multiple sclerosis. The future of Tysabri was threatened, however, as it had been removed from the market in February 2005 after two patients taking it died from a rare neurological disorder. Tysabri was back on the market by September 2006, but only pursuant to a rigorous program to monitor the drug for further side effects. By the start of the Class Period, sales of Tysabri had only slowly begun to recover. At the same time, the sales of a number of Elan’s other drugs were plummeting due to generic competition. As a result, Elan’s future hinged upon the safety and effectiveness of bapineuzumab, also called AAB-001, a drug Elan was developing in association with Wyeth for the treatment of Alzheimer’s disease. Indeed, according to the *Associated Press*, Elan was “banking on an Alzheimer’s breakthrough for its future growth.”

3. The demand for a safe and effective Alzheimer’s treatment is enormous. Over four million people suffer from the disease in the United States alone. Current treatments reduce symptoms, but do not slow or stop the progression of the disease. As of May 2007, no treatments had proven to be “disease modifying,” meaning that they could reverse or halt the progression of Alzheimer’s. For that reason, among others, some analysts estimated that only 35% of Alzheimer’s patients in developed countries worldwide are on medication for the condition. Recognizing the huge and lucrative market for the treatment of Alzheimer’s, during the Class Period *Barrons* called

bapineuzumab “potentially ‘the biggest drug of all time’” and analysts characterized its prospects as the principal mover behind the price of Elan securities.

4. In order to win approval for bapineuzumab from the Food and Drug Administration (“FDA”), Elan planned to conduct both Phase 2 and Phase 3 clinical trials. Phase 2 trials are designed to assess the dosing requirements, the efficacy at particular doses, and the safety of a drug on a medium-sized group of patients (roughly 30 to 300). Phase 3 trials expand the safety and efficacy assessment to a larger group of patients (generally 300 to 2,000) and often for a longer period of time.

5. In April 2005, defendants were to begin a Phase 2 clinical trial of bapineuzumab versus placebo involving 240 patients (the “Phase 2 Study”). Before the Phase 2 Study commenced, Elan and Wyeth agreed that they would conduct an “interim review” of the Phase 2 Study results before the study was complete in order to determine whether and how to proceed with Phase 3 studies. Elan and Wyeth agreed that they would initiate Phase 3 studies before the Phase 2 Study was completed if, and only if, the interim review showed that bapineuzumab was significantly outperforming placebo in the Phase 2 Study. In order to assess bapineuzumab in the interim review, Elan and Wyeth agreed to use the two primary tests used in the study, the Alzheimer’s Disease Assessment Scale-Cognitive Subscale (“ADAS-cog”) and the Disability Assessment Scale for Dementia (“DAD”).

6. Defendants informed investors that in order for Elan and Wyeth to initiate Phase 3 studies before the Phase 2 Study was complete, bapineuzumab would have to overcome the high hurdle of the interim review. For example, defendants stated that “Wyeth and ourselves have agreed to certain very specific criteria that need to be met in this Phase II trial in order to propel us

into Phase III.” In order to meet these criteria, defendants told investors that the interim results of the Phase 2 Study would have to be “spectacular,” “strong,” and “very meaningful.”

7. Defendants conducted the interim review of the Phase 2 results in May 2007 and were gravely disappointed. The results were neither spectacular nor strong. Bapineuzumab did not outperform placebo as required using the ADAS-cog and DAD tests. Further, higher doses of the drug were associated with vasogenic edema, a potentially dangerous accumulation of fluid in the brain, in patients that carried the Apolipoprotein E4 (“ApoE4”) allele. Although bapineuzumab failed the interim review, the results were not entirely discouraging. Defendants noticed that ApoE4 non-carriers seemed to perform better on bapineuzumab than carriers of the allele. Non-carriers represent 40-70% of the Alzheimer’s population and thus a smaller but still potentially profitable potential market.<sup>1</sup>

8. Despite having told investors that they would not proceed with Phase 3 studies before the Phase 2 Study was complete unless bapineuzumab passed the strict criteria of the interim review, defendants decided to proceed with the very expensive Phase 3 trials even though it had failed. Defendants’ reasoning was simple: the huge potential windfall of an effective Alzheimer’s drug, even if it only worked on those without ApoE4, was so massive that it warranted the risk of proceeding to Phase 3 notwithstanding that the drug had failed the interim review. Accordingly, defendants began to design Phase 3 trials that separated ApoE4 carriers from non-carriers and that did not use the high two-milligram dose of bapineuzumab that had been associated with vasogenic edema in ApoE4 carriers.

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<sup>1</sup> Oddly, individuals carrying ApoE4 had previously been shown to be **more** likely to develop Alzheimer’s. It was thus counter-intuitive that bapineuzumab would appear to work better in patients who failed to carry ApoE4.

9. Defendants did not inform investors that, contrary to their previous statements, they were disregarding the failed interim review. Instead, on May 21, 2007, the first day of the Class Period, they simply announced that they were initiating Phase 3 trials, thus communicating to investors that bapineuzumab had met the strict criteria of the interim review with strong and spectacular results. Accordingly, after defendants announced the initiation of Phase 3 studies, the price of Elan's ADRs jumped 12.5% in one day, to over \$12.

10. Defendants concealed the disappointing results of the interim review because it was critically important that they enroll the Phase 3 trials as quickly as possible. These trials required over 4,000 Alzheimer's patients willing to take a chance on an experimental drug and the sooner they could be fully enrolled and completed, the sooner defendants had a chance of getting bapineuzumab approved. Patients are much more likely to enroll in a study regarding a highly promising new drug than one that has previously shown mixed results. Accordingly, defendants concealed that bapineuzumab had failed the interim review and led everyone to believe that the results of the review were strong and spectacular instead. Although defendants would eventually have to disclose the final results of the Phase 2 Study, they would not have to do so for at least a year, giving them plenty of time to enroll patients in the Phase 3 trials first. Further, there was always the chance that the final results of the Phase 2 Study would be better than those observed at the interim review.

11. They were not. When the Phase 2 Study was completed in April 2008, bapineuzumab failed to outperform placebo to a statistically significant degree on the ADAS-cog and DAD. Further, the drug showed no dose response, meaning that higher doses of the drug did not correlate with greater improvement of symptoms. To the extent bapineuzumab outperformed placebo at all, it may have been because the non-carrier patients taking placebo got worse much

faster than expected, thus making bapineuzumab's results look better. And, in addition to vasogenic edema, there were a host of other potentially troubling side effects associated more strongly with bapineuzumab than placebo.

12. Defendants were loathe to admit the disappointing final results of the Phase 2 Study. To begin with, the Phase 3 studies were still enrolling, and any negative news about bapineuzumab would delay their completion and thus the possible approval of the drug and the revenues that would follow. Further, they did not want to admit to having misled the public, including investors, about the results of the interim review. Unfortunately for defendants, investors were clamoring for the results of the study. Accordingly, defendants scheduled a presentation at the Alzheimer's Association's International Conference on Alzheimer's Disease 2008 ("ICAD") in Chicago, Illinois. Several weeks before the full study results were disclosed at ICAD, however, defendants decided to announce the positive ApoE4 non-carrier results first. This would give investors and everyone else several weeks to consider the value of a potentially effective Alzheimer's drug for ApoE4 non-carriers and hopefully blunt the effect of the negative results of the Phase 2 Study.

13. Thus, on June 17, 2008, defendants issued a press release announcing that in the Phase 2 Study patients without ApoE4 performed better on bapineuzumab than placebo to a statistically significant degree. The release acknowledged that patients with ApoE4 did not do so, but it failed to disclose the magnitude of the miss, the absence of dose response, the unusually swift decline of the placebo patients, or the troubling safety results. As a result, the price of Elan's ADRs jumped another 10% in one day.

14. On July 29, 2008, the full results of the Phase 2 Study were presented at ICAD. At that conference and in a concomitant press release and conference call, investors learned for the first time that:

- (a) The Phase 2 Study showed no dose response;
- (b) Among the group in which some evidence of bapineuzumab's efficacy was purportedly found, the patients taking placebo showed a larger than expected cognitive decline. If the placebo group deteriorated more rapidly than average patients, this would exaggerate the efficacy results of bapineuzumab in the study;
- (c) In order to manufacture bapineuzumab's statistically significant outperformance of placebo in the Phase 2 Study, defendants changed the statistical model *post hoc* from linear to curvilinear. The original trial protocol called for linear modeling. Had defendants not changed to a curvilinear model without informing investors, they could not have claimed that bapineuzumab outperformed placebo by a statistically significant margin, even in the ApoE4 non-carrier group;<sup>2</sup>
- (d) Although the Phase 2 Study showed bapineuzumab to outperform placebo in some patients over 18 months, there was no short-term advantage for bapineuzumab;
- (e) Using the Mini Mental State Examination ("MMSE"), which defendants characterized as a "key measure of cognitive function," there was no significant signal in the Phase 2 Study that bapineuzumab worked better than the placebo;
- (f) Nearly 10% of the patients in the Phase 2 Study (12 patients) taking bapineuzumab developed vasogenic edema versus zero patients in the placebo group (three of the patients so affected also developed bleeding in their brains);

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<sup>2</sup> *Post hoc* analyses, meaning those devised after the data has been unblinded, are less reliable than those designed prospectively for the simple reason that *post hoc* analyses may be tailored to fit the data in order to generate whatever outcome is sought.

(g) Three deaths were reported in the group taking bapineuzumab compared to none in the placebo group. One of the deaths was caused in part by an aortic dissection (a tear in the wall of this major artery) which has the potential to be related to drugs such as bapineuzumab; and

(h) There were nine additional adverse effects that occurred two or more times as often in patients taking bapineuzumab versus placebo and in more than 5% of such patients, including, anxiety, vomiting, hypertension, paranoia, skin laceration, gait disturbance, and muscle spasms; and

(i) Bapineuzumab not only failed to show a statistically significant benefit compared to placebo per the original trial protocol, but failed to do so by a large margin.

15. When these facts were finally disclosed, the price of Elan's ADRs plunged 42% in one day as the artificial inflation caused by defendants' false and misleading statements came out of the price. Far from being "strong" and "spectacular," the adverse results of the Phase 2 Study were a material setback for the developments of bapineuzumab. They meant that the Phase 3 trials would likely have to run their full 18-month courses before any FDA approval was possible. Indeed, the disappointing results of the Phase 2 Study virtually eliminated any chance that Elan could receive FDA approval before the Phase 3 trials were finished. Even if bapineuzumab were eventually approved by the FDA, this delay of many months or even years (depending on how fast the Phase 3 studies enrolled) pushed any revenues further into the future and reduced their then-present value. Finally, the previously undisclosed and negative Phase 2 Study data reduced the likelihood that bapineuzumab was greatly superior to Alzheimer's drugs already on the market, limiting its commercial potential. Nonetheless, even after the disclosure of the full results of the Phase 2 Study, the price of Elan securities continued to trade at artificially inflated prices due to

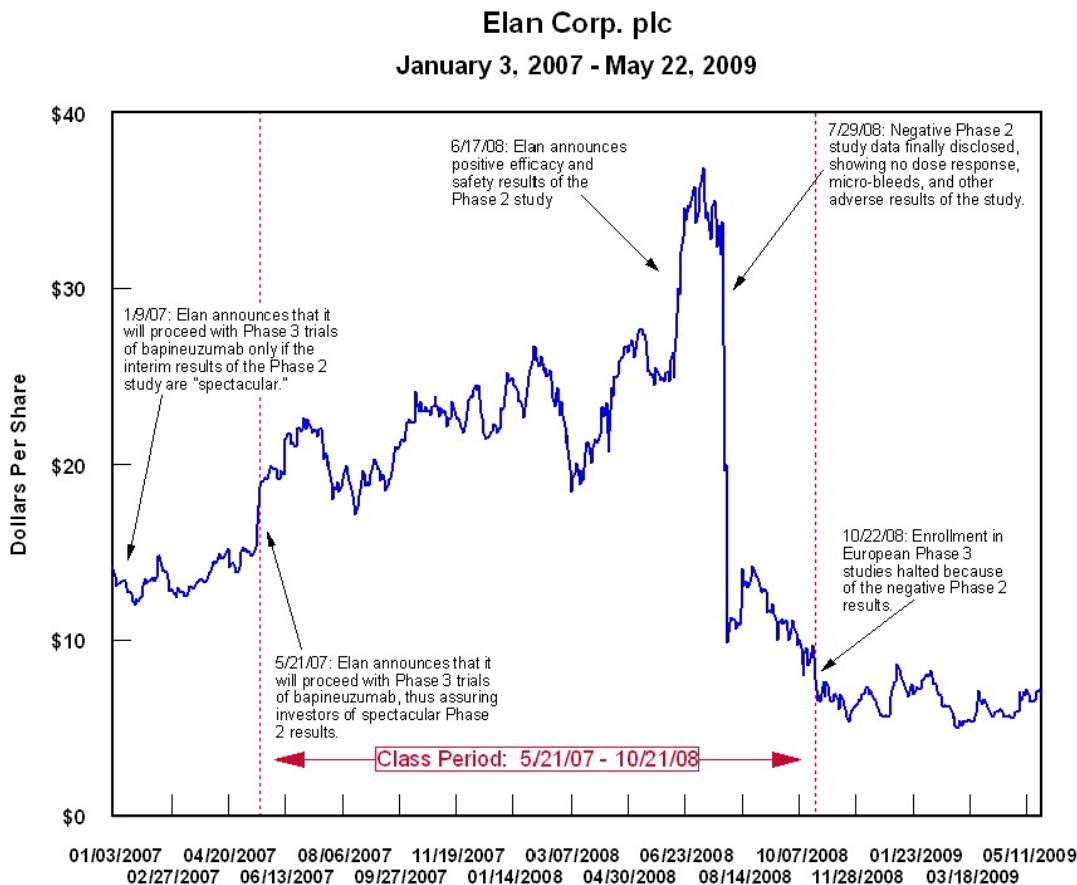
defendants' false and misleading statement that "the Phase 2 data reinforce the design of the ongoing Phase 3 studies." In fact, the Phase 2 data caused a significant delay in those studies.

16. Finally, on October 22, 2008, Elan's partner in the development of bapineuzumab, Wyeth, disclosed in a conference call that European regulators had ordered that two Phase 3 studies of bapineuzumab be delayed in light of the adverse results of the Phase 2 Study. On this news, Elan's ADRs declined from \$9.06 per share to \$7.82 per share in one day, a decline of more than 13%, as artificial inflation came out of the price. All told, Elan's ADRs had dropped 79% from their Class Period high of \$36.82 following defendants' June 17, 2008 press release, and investors suffered hundreds of millions of dollars in damages.<sup>3</sup>

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<sup>3</sup> Phase 3 studies of bapineuzumab are now ongoing. Regardless of the results of these studies, during the Class Period, defendants misstated the results of the Phase 2 Study and failed to disclose material information from that study about the safety and efficacy of bapineuzumab.

17. The following chart presents the price of Elan's ADR's before, during, and after the Class Period:



#### JURISDICTION AND VENUE

18. The claims asserted arise under §§10(b) and 20(a) of the Securities Exchange Act of 1934 ("1934 Act"), 15 U.S.C. §§78j(b) and 78t(a), and Rule 10b-5, 17 C.F.R. §240.10b-5, promulgated thereunder. Jurisdiction is conferred by §27 of the 1934 Act, 15 U.S.C. §78aa.

19. Venue is proper here pursuant to §27 of the 1934 Act. Elan conducts business in this District and its ADRs trade on the NYSE, which is located in this District. During the Class Period, Elan's CEO, defendant G. Kelly Martin, was headquartered in this District and he continues to reside here. Also, the Phase 2 Study at issue was conducted, in part, in this District.

## THE PARTIES

20. Lead Plaintiff Luc Lemmerling (“Lemmerling”) is a United States resident who purchased ADRs listed and trading on the NYSE during the Class Period in accordance with the Certification attached as Exhibit A. As further described herein, the price of Lemmerling’s ADRs were inflated for the wrongdoing alleged herein, and when the truth was revealed, the inflation in the ADRs’ prices was removed and Lemmerling suffered losses as a result thereof.

21. Plaintiff Plumbers & Steamfitters Local 773 Pension Fund (“Plumbers”) is located in South Glenn Falls, New York. As identified in the certification filed with the Court on October 14, 2008, Plumbers purchased Elan ADRs listed and trading on the NYSE. As a result of the wrongdoing alleged herein, Plumbers purchased the ADRs at inflated prices during the Class Period and when the truth was revealed, the inflation in the ADRs’ prices was removed and Plumbers suffered losses as a result thereof.

22. During the Class Period, defendant Elan maintained operations at 875 Third Avenue, 3rd Floor, New York, New York and the Company’s ADRs traded on the NYSE and the London Stock Exchange (“LSE”), which are efficient markets.<sup>4</sup> Eighty-seven point seven percent (87.7%) of Elan’s equities trade on the NYSE in the form of ADRs. During the Class Period, Elan’s CEO was based in New York, New York, the Company’s research and communication functions were based in San Francisco, California, and its general counsel was in Pennsylvania. The bulk of the Company’s employees, including nearly all of its researchers, were and continue to be in the United States.

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<sup>4</sup> Elan’s ADRs ceased trading on the LSE in October 2007.

23. Defendant G. Kelly Martin (“Martin”) was Elan’s President and CEO at all relevant times. Martin resides in New York, New York.

24. Defendant Lars Ekman (“Ekman”) was Elan’s President of Research and Development during the Class Period until December 31, 2007, and was a member of the Board of Directors and Chairman of the Science and Technology Committee of the Board throughout the Class Period. Ekman resides in La Jolla, California.

25. The defendants identified in ¶¶23-24 are referred to herein as the Individual Defendants.

## **BACKGROUND**

26. Alzheimer’s disease is a progressive brain disorder that gradually destroys a person’s memory and ability to learn, reason, make judgments, communicate, and carry out activities of daily living. As Alzheimer’s disease progresses, individuals may also experience changes in personality and behavior, such as anxiety, suspiciousness, or agitation, as well as delusions or hallucinations. Alzheimer’s disease is one of many forms of dementia. It affects the brain’s physical structure and is characterized by the presence of amyloid plaques and neurofibrillary tangles.

27. Scientific evidence suggests that a peptide called beta amyloid plays a role in the pathology of Alzheimer’s disease. One approach to slowing or stopping the course of Alzheimer’s disease may lie in clearing beta amyloid from the brain.

28. Bapineuzumab was designed to clear toxic beta amyloid from the brain, with the hope that this might slow or prevent the progressive neurodegeneration in the brain associated with Alzheimer’s disease.

29. For more than eight years, Elan and Wyeth’s Alzheimer’s Immunotherapy Program actively pursued treatments based on the beta amyloid hypothesis without any commercial success.

By 2006, bapineuzumab was the most promising compound being developed by Wyeth and Elan through their Alzheimer's Immunotherapy Program.

30. As part of that program, Elan and Wyeth conducted the Phase 2 Study, an 18-month clinical trial of bapineuzumab, at the following research centers in the U.S.:

Arizona:

- Cleo Roberts Center for Clinical Research/SunHealth Research Institute, Sun City, Arizona

California:

- Pharmacology Research Institute, Los Alamitos, California
- Pharmacology Research Institute, Northridge, California
- Memory & Aging Center, UCSF, San Francisco, California
- UC Irvine, Irvine, California
- UCSD Shiley-Marcos Alzheimer's Disease Research Center, San Diego, California

Connecticut:

- Yale University School of Medicine, New Haven, Connecticut

District of Columbia:

- Georgetown University Medical Center, Washington, D.C.

Florida:

- Brain Matters Research, Inc., Delray Beach, Florida
- Mayo Clinic, Department of Neurology, Jacksonville, Florida

Illinois:

- Rush Presbyterian St. Luke's Medical Center, Chicago, Illinois

Indiana:

- Department of Neurology, Indiana University Medical Center, Indianapolis, Indiana

Massachusetts:

- Behavioral Neurology, Boston, Massachusetts

Michigan:

- University of Michigan Health System, Department of Neurology, Ann Arbor, Michigan

Minnesota:

- Mayo Clinic Department of Neurology, Alzheimer's Disease Research Center, Rochester, Minnesota

New Jersey:

- The Memory Enhancement Center, Long Branch, New Jersey

New York:

- University of Rochester/Monroe Community Hospital, Rochester, New York
- Sergievsky Center, Columbia University, New York, New York

North Carolina:

- Department of Psychiatry and Behavioral Sciences, Durham, North Carolina

Oregon:

- Oregon Health and Science Center, Portland, Oregon

Pennsylvania:

- University of Pittsburgh, Pittsburgh, Pennsylvania

Rhode Island:

- Memory and Aging Program, Butler Hospital, Providence, Rhode Island

Texas:

- University of Texas Southwestern Medical Center, Dallas, Texas
- Baylor College of Medicine, Houston, Texas

Vermont:

- Clinical Neuroscience Research Associates, Inc., Bennington, Vermont

Washington:

- University of Washington, Seattle, Washington

31. Each participant in the study took bapineuzumab or a placebo for 18 months.

Because patients enrolled in the Phase 2 Study on a rolling basis, the study, which was initiated in April 2005, was not completed until April 2008.

32. The Phase 2 Study was designed to measure the efficacy of the drug compared to placebo using a number of different tests. The two primary tests were the ADAS-cog and the DAD. If bapineuzumab performed statistically significantly better than placebo pursuant to these two tests, then, and only then, the study would have met its “primary endpoint” and could support a claim that bapineuzumab is demonstrably effective. The Phase 2 Study also included, as additional tests, changes in cerebral spinal fluid, changes in brain volume, the Neuropsychological Test Battery, Clinical Dementia Rating Sum of Boxes, and MMSE.

#### **PRE-CLASS PERIOD EVENTS**

33. On May 4, 2006, Elan issued a press release announcing its first quarter 2006 financial results. That release also stated: “The Phase 2 clinical trials for AAB-001 [bapineuzumab] . . . are progressing as planned. Interim analyses of Phase II data from AAB-001 will be made . . . to determine the time point at which this program can move into the next phase of clinical trials.”

34. On October 5, 2006, Wyeth held a conference call with financial analysts at which Bob Ruffolo, a Senior Vice President of Wyeth and the President of Wyeth Research, discussed the Phase 2 Study it was co-sponsoring with Elan. Specifically, Mr. Ruffolo told the analysts “we don’t have any results from this study at all, but we have a planned interim look at the data . . . And, based on this interim look, we could do two things. One, depending on the data, we could advance directly into phase III in the first half of 2007, ***but the results would have to be spectacular.***”

35. On January 9, 2007, defendants Martin and Ekman made a presentation at JP Morgan's 25th Annual Healthcare Conference in San Francisco, California, and also stated that Elan and Wyeth would perform an "interim" analysis of the results of the Phase 2 Study. Defendants stated that they would initiate Phase 3 studies of bapineuzumab only if the results met the very specific, predetermined criteria of the interim analysis that required "strong" and "spectacular" results. Specifically, defendants made the following statements:

[Martin]: AAB-001, the data we shared from Phase I and there's other data we haven't shared, but the data that we have shared shows significant improvement in memory after four months on one dose. That was presented in Geneva in 2006.

The Phase II trial, just to repeat what it is, it's a multiple ascending dose trial. There's 240 patients. There's another PET program, which has got 30 patients. We've got four different clinical endpoints to the trial, cognition, memory, quality of life and imaging. It's a very important trial. I think it's important for me to emphasize a number of things about this trial. First and foremost, this was deemed fast tracked by the FDA last year. That's number one. Number two, it was also deemed as potentially a pivotal trial by the FDA last year. That's number two.

Number three, because it could be a pivotal trial, it's very important that we maintain the integrity of both the data and the trial itself as we move forward. We also have agreement, Wyeth, ourselves and the FDA, about trying to look at parts of the data in a very controlled manner that will be administrative in nature, independent of both Elan and Wyeth and allow us to tease out information that would help us design the follow-on Phase III trial. It's very programmed, it's very controlled. It's something that Wyeth, ourselves and the FDA have worked on.

And then, lastly, the important thing to emphasize is that ***Wyeth and ourselves have agreed to certain very specific criteria that need to be met in this Phase II trial in order to propel us into Phase III.***

\* \* \*

What we've given the independent review group is very specific criteria that we're looking for. And we came up with that criteria by looking at a vast array of data, some of which I went through a little while ago that lets us anticipate which of these endpoints are going to move when and to what amplitude.

\* \* \*

[Martin]: Lars? The question is that, if I can paraphrase a little bit, towards the end of '06, there was an impression in the market that they would hear

something, go, no go, for AAB-001. What do we think of that and what is the process going forward? So I'll ask Lars Ekman to answer that.

Lars Ekman – Elan Pharmaceuticals – EVP and President, Global R&D, Head of Neurodegeneration Franchise:

We have defined a specific process by which we can in certain instances look at the data. As Kelly said, it's extremely controlled, because we have identified this trial as pivotal. That means we can't jump in and out of the data at our leisure, which you could if it was a non-pivotal Phase II study.

We have also said that once we get positive data, we will inform the market. When you do these trials, it's a dose-escalation trial, so you start with the very low doses and then you move upward. And you start to look at the low doses at the shortest possible time and then you move upwards. And this is a trial that will continue through 2007 and during that time there will be interim looks.

We have also jointly with Wyeth decided that we will not comment on when and how we're going to do the interim looks. *We will inform the market when we have met the hurdles that we jointly set. And to paraphrase Bob Ruffalo, he said the data has to be – he used the word spectacular. I use the word it has to be strong, it has to be very meaningful.*

*There are companies that decide to move into Phase III based on circumstantial evidence of efficacy, et cetera, but that's not the way we're going to operate.*

36. On February 20, 2007, Goodbody Stockbrokers published an analyst report which stated in part:

- In the short to medium term, the company is dependent on both the progress of Tysabri in the market for the treatment of MS and AAB-001 [bapineuzumab] in the pipeline for Alzheimers.

\* \* \*

- On AAB-001 [bapineuzumab], we are awaiting a second look at the data from patients currently on a Phase II trial. This will take place in mid-2007 and will determine whether or not a Phase III trial can be initiated before the current Phase II trial concludes. This is due in late 2007/early 2008. A positive outcome from the mid-2007 "look" would augur well for the drug.

#### **CLASS PERIOD EVENTS AND STATEMENTS**

37. On May 21, 2007, investors and analysts were led to believe that the results of the Phase 2 Study met the strict, predetermined criteria of the interim analysis, which required "strong"

and “spectacular” data, when defendants and Wyeth issued a press release announcing the initiation of Phase 3 clinical trials of bapineuzumab. The release stated in part:

Elan Corporation, plc and Wyeth Pharmaceuticals, a division of Wyeth, today announced the decision to initiate a Phase 3 clinical program of their lead immunotherapeutic candidate, bapineuzumab (AAB-001), for the treatment of patients with mild to moderate Alzheimer’s disease. *This decision was based on the seriousness of the disease and the totality of what the companies have learned from their immunotherapy programs, including a scheduled Interim look at data from an ongoing Phase 2 study*, which remains blinded. No conclusion about the Phase 2 study can be drawn until the study is completed and the final data are analyzed and released in 2008. Phase 3 clinical trial design will be finalized with regulatory agencies, and subject to regulatory approval, it is intended for the trial to begin in the second half of 2007.

38. As a result of the announced initiation of Phase 3 trials and, by implication, the successful interim review based upon supposedly strong and spectacular results of the Phase 2 Study, the price of Elan ADRs increased from \$16.60 on the previous trading day to close at \$18.69, a 12.5% increase, reflecting the artificial inflation caused by defendants’ false and misleading statements.

39. On May 21, 2007, Davy Research published an analyst report which stated, in part:

- Elan and Wyeth have taken a major step forward in the development of their lead Alzheimer’s Disease (AD) candidate, Bapineuzumab (AAB-001). The product will proceed to Phase III studies on an accelerated basis, 6-12 months ahead of the typical schedule.
- No data have been disclosed, *but both companies previously outlined that results from the Phase II interim analyses would need to be “spectacular” to proceed.*

40. On July 31, 2007, Natixis Bleichroeder Inc. published an analyst report which stated in part:

- Since Elan and Wyeth announced they were starting Phase III on bapineuzumab after an interim look at its Phase II data in May, there has been much speculation as to how good the data are, given that the trial is still blinded.

- We think the data at the interim look must have been profound and possibly involved a continual separation of drug from placebo over time – indicative of true disease modification.

41. Defendants' May 21, 2007 press release was materially false and misleading because the results of the Phase 2 Study at the time of defendants' interim analysis were not strong and spectacular as defendants said they had to be before Elan would proceed with Phase 3 trials. In fact, bapineuzumab failed to outperform placebo using the ADAS-cog and DAD in the interim review as required by Elan and Wyeth's prior agreement. Further, vasogenic edema was associated with high doses of bapineuzumab in ApoE4 carriers.

42. Following the May 21, 2007 press release, defendants continued to assert that the Phase 3 studies were proceeding based upon defendants' interim review of the Phase 2 Study and the purportedly spectacular results of that study. For example, during a July 26, 2007 conference call with analysts, defendant Ekman stated that: "The decision to move into Phase III was based on the totality of what the companies have learned from our Alzheimer's immuno therapy programs, including the scheduled interim look at data from our ongoing Phase II study . . ." Such statements kept Elan securities trading at artificially inflated levels above \$17 per share. At no time did defendants disclose the results of the Phase 2 Study they knew to be disappointing, as set forth in ¶41.

43. On April 28, 2008, Natixis Bleichroeder published an analyst report regarding Elan which stated in part:

The only truly new thing that came out of the Q1 call last week was that Elan ***definitively*** stated that it will present the full data set from the bapineuzumab Phase II triad at ICAD at the end of July. . . . This signals to us that the end of the study is right on track to have top-line results put out in a press release in June. . . . [W]e believe Elan will do its best to communicate that these results remove the majority of the risk of failure, and it should be clear this is an approvable drug. ***These events should also rapidly accelerate enrollment in the Phase III studies.***

44. On May 1, 2008, defendant Martin made a presentation to investors at the Morgan Stanley 2008 Global Healthcare Unplugged Conference in Miami, Florida, during which he responded to investor questions regarding bapineuzumab as follows:

Unidentified Audience Member:

Hi, if I could just ask a bapineuzumab question.

You guys have talked about in the past that you would go into Phase III, only really on the basis of really clinically meaningful and even spectacular data and you've also indicated possibly being able to file sub par E on the Phase IIB data, the final data. I guess I'm trying to understand, what does that mean? Those qualitative descriptions. Does that mean we should expect statistical significance on Phase II? Does that mean we should expect trends? What exactly is spectacular?

[Martin]:

Spectacular is probably in the eyes of the beholder, but what we said before we moved into Phase III, that we would need to see clinically meaningful data. We have looked at with Wyeth and ourself – when I say we, Wyeth and ourselves, we looked at all the immunotherapeutic information, going back to the original IA in 1792. Looking at the Phase I data, looking at the interim Phase II data, et cetera.

When we took an interim look, we clearly were looking for some specific things from a clinical point of view. There was a number of end points that we were looking at. We looked at it at a period of time that was still fairly early on in the Phase II. So we both – we looked for both specific points and specific trends in certain things and we put that together and we had discussions with both the European agency and the U.S. agency, the collective decision was we should move to a Phase III, simultaneously.

We've kept the Phase II blinded because there is some chance, although again, as I've said to many people, it's not a high probability, but it is a probability. Or some probability, that the – *if the Phase II data is really spectacular that there could be some regulatory pathway to a filing that would be earlier than a full normal completion of Phase III*. That's going to depend, obviously on the data, its going to depend on discussions with the regulator etc.

So what you should – what I believe that you should expect to see, what we would like you to see is that *once you see the Phase II data, the marketplace and the investigators, the clinicians and everyone else who wants to look at it would say, geez, I understand exactly why Wyeth and Elan started a Phase III earlier than they did.*

I understand exactly why the Phase II remained blinded for the balance of the trial, and that from that you can draw your own conclusions from a confidence level

about – based on the Phase III design, which is public and the Phase II data, you can put those two together and decide individually, collectively, the probability of having a drug and the pathway to having the drug, whether it's a combination two/three or three on its own will have to be determined with regulatory discussions.

\* \* \*

Unidentified Audience Member:

So, just to be clear on the question of whether we should expect significance or not, understanding that this is a relatively small study and particularly at the interim it was even smaller data set you had to look at. Would we expect significance in any one dose, would we expect significance in all three of the doses that you eventually took into Phase III. Would we expect significance on maybe a combined analysis of those three dosing cohorts or should we just not expect any kind of statistical significance and just pay attention to trends. How would we look at – how would you want us to look at it?

[Martin]:

I think it should be very obvious when we move to Phase III. So, without answering that specifically, I think it will be – *it should be obvious why we moved to Phase III* and I think that whether its statistical significance in all or parts, supported by trends, or trends with different combinations of data points. *I think that the reason we moved to Phase III was we clearly saw enough data to move forward. It's a huge decision for us, and for Wyeth and its one that we don't take lightly.*

And I also remind people that Elan has been working on immunotherapy for 20 years. So, as much pressure as there is to get to the last piece of information for the Phase II, we're not going to screw it up because we have a lot of other things in immunotherapy which we think are going to be relevant for years to come.

So we are as anxious as anybody to look at the Phase II data, we've done a lot of work internally trying to predict what it would be. But our goal would be that as participants in the marketplace, that when you see the Phase II data, that there's unequivocal evidence why we moved to Phase III. Whether it's statistical in everything, some things or combinations of statistical plus trends, our goal would be that it would be very clear to all of you sort of why we moved to Phase III.

I also say to people, it would have been far easier for me, sitting here, to say we moved to Phase III and here's all the data. Because for a year we've been trying to answer the questions in a way that's helpful for investors, but keep the Phase II pure.

So, if you want to take it from that point of view, clearly we saw enough between Wyeth and ourselves and the agencies that, we have attempted, I think, pretty well to try to keep Phase II as blinded as possible and start to Phase III. And also, by the design of the Phase III, by definition, we're giving a lot of information

out as far as what we saw. So, we're very much looking forward to sharing the Phase II data.

45. Martin's statements set forth in the above paragraph were materially false and misleading because the results of the Phase 2 Study at the time of defendants' interim analysis were not strong and spectacular as defendants said they had to be before Elan would proceed with Phase 3 trials. In fact, bapineuzumab failed to outperform placebo using the ADAS-cog and DAD in the interim review as required by Elan and Wyeth's prior agreement. Further, vasogenic edema was associated with high doses of bapineuzumab in ApoE4 carriers.

46. As a result of defendants' May 1, 2008 false and misleading statements, Elan's stock continued to trade at an artificially inflated level.

47. On May 21, 2008, Davy Research published an analyst report which stated in part:

- Further discussions with Elan's senior management team ahead of the company's AGM on May 22nd indicated a continued strong level of confidence in the prospects for its AD pipeline, and in particular Bapineuzumab. Although nothing new was divulged on the pipeline, several key points were reiterated.
- The Phase II data on Bapineuzumab will make it clear why Elan/Wyeth moved early into Phase III. We would interpret this as a clear message on the drug's efficacy together with a safety profile that is consistent with what we know from previous trials.

48. On June 17, 2008, defendants and Wyeth issued a press release which stated the following:

Elan Corporation, plc and Wyeth today announced encouraging preliminary findings from a Phase 2 study of bapineuzumab (AAB-001) in patients with mild to moderate Alzheimer's disease. In the 18-month trial, bapineuzumab appeared to have clinical activity in treating Alzheimer's disease.

#### Efficacy Findings

The study did not attain statistical significance on the primary efficacy endpoints in the overall study population. Post-hoc analyses did show statistically significant and clinically meaningful benefits in important subgroups.

In non-carriers of the Apolipoprotein E4 (ApoE4) allele, estimated in the literature to be from 40 to 70 percent of the Alzheimer's disease population, post-hoc analyses showed statistically significant and clinically meaningful benefits associated with bapineuzumab treatment on several key efficacy endpoints, including the Alzheimer's Disease Assessment Scale (ADAS-cog), the Neuropsychological Test Battery (NTB), the Mini Mental State Examination (MMSE) and the Clinical Dementia Rating – Sum of Boxes (CDR-SB). A favorable directional change was seen on the Disability Assessment Scale for Dementia (DAD), although this was not statistically significant.

\* \* \*

### Safety Findings

As expected given the nature of the population studied, adverse events were very common in both placebo and bapineuzumab-treated patients. In non-carriers, the number of patients experiencing serious adverse events was similar between placebo and bapineuzumab-treated patients. In carriers, serious adverse events were more frequently observed in bapineuzumab-treated patients than in placebo patients. In addition, vasogenic edema was reported in the treated population with an increased frequency in carriers and at higher doses. No cases were reported in placebo patients. In the ongoing Phase 3 studies, carriers of the ApoE4 allele are being treated with a lower dose to minimize the risk of vasogenic edema. The Companies believe that the overall safety findings from this Phase 2 trial support their prior decision to move to Phase 3 studies.

### CEO Comments

"The preliminary analyses of the Phase 2 study are a continued validation of the amyloid approach to Alzheimer's disease and an important milestone in our companies' ongoing commitment to bring new treatment options to patients," said Kelly Martin, President and CEO of Elan. "These results clinically support our decision to move into Phase 3 last year."

\* \* \*

These findings reflect preliminary analyses of the Phase 2 data and its implications for ongoing clinical development of bapineuzumab. In this trial, there were imbalances in patient numbers and characteristics at baseline between subgroups studied that may or may not have affected these results. Further analysis will continue in advance of a planned scientific presentation of detailed results of this study at the International Conference on Alzheimer's Disease (ICAD) in Chicago, July 29, 2008.

49. As a result of these statements, the price of Elan's ADRs shot from \$27.11 to \$30 in one day, an increase of over 10% as Elan securities continued to trade at artificially inflated prices.

By July 10, 2008 Elan's ADRs were trading at over \$36, more than 120% higher than they traded prior to the Class Period.

50. Defendants' June 17, 2008 press release was materially false and misleading because it failed to disclose the known, materially adverse results of the Phase 2 Study. Specifically, defendants failed to disclose that:

- (a) The Phase 2 Study showed no dose response, meaning that taking higher doses of bapineuzumab did not correlate with greater improvement in symptoms;
- (b) Among the subset of patients in which some evidence of bapineuzumab's efficacy was purportedly found, the patients taking placebo showed a larger than expected cognitive decline. If the placebo group deteriorated more rapidly than average patients, this would exaggerate the efficacy results of bapineuzumab in the study;
- (c) In order to manufacture bapineuzumab's statistically significant outperformance of placebo in the Phase 2 Study, defendants changed the statistical model *post hoc* from linear to curvilinear. The original trial protocol called for linear modeling. Had defendants not changed to a curvilinear model without informing investors, they could not have claimed that bapineuzumab outperformed placebo by a statistically significant margin, even in the ApoE4 non-carrier group;
- (d) Although the Phase 2 Study showed bapineuzumab to outperform placebo in a subset of the patient population over 18 months, there was no short-term advantage for bapineuzumab;
- (e) Using the MMSE, which defendants characterized as a "key measure of cognitive function," there was no significant signal in the Phase 2 Study that bapineuzumab was more efficient than the placebo;

(f) Nearly 10% of the patients in the Phase 2 Study (12 patients) taking bapineuzumab developed a potentially dangerous accumulation of fluid in the brain known as vasogenic edema versus zero patients in the placebo group (three of the patients so affected also developed “micro bleeds” in their brains);

(g) Three deaths were reported in the group taking bapineuzumab compared to none in the placebo group. One of the deaths was caused in part by an aortic dissection (a tear in the wall of this major artery) which has the potential to be related to drugs such as bapineuzumab; and

(h) There were nine additional adverse effects that occurred two or more times as often in patients taking bapineuzumab versus placebo and in more than 5% of such patients, including, anxiety, vomiting, hypertension, paranoia, skin laceration, gait disturbance, and muscle spasms; and

(i) Bapineuzumab not only failed to show a statistically significant benefit compared to placebo per the original trial protocol, but failed to do so by a large margin.

51. On June 17, 2008, Credit Suisse published an analyst report entitled “Key Alzheimer’s data read encouraging,” which stated in part:

- The eagerly awaited data for AAB-001 (bapineuzumab) came with some encouraging indications of efficacy this morning, with the company reporting a statistical benefit after 18 months in a subgroup that does not carry the APOE 4 gene (around 50% of mild to moderate AD patients). . . .
- Although this is a small trial and the post hoc subgroup statistical analysis is weaker than prospectively defined statistically analysis, some investors may gain more confidence that the effects of AAB-001 on cognition seem robust. This is because reported statistical benefits on cognition in the APOE4 non-carrier group were replicated in three independent and validated cognitive tests (ADAS-cog, NTB, and MMSE). . . .

52. On June 17, 2008, Natixis Bleichroeder published an analyst report entitled “ELN: No Negative Babby Data Keeps Us Happy,” which stated in part:

The long-awaited Phase II bapineuzumab data were unleashed in a press release early this morning, and although the release contained scant numbers, the data were very encouraging.

53. On June 18, 2008, Davy Research published an analyst report entitled “Bapineuzumab provides better-than-expected subset data: risked valuation upgraded to \$31.” The report stated in part:

**Becoming more confident on development and commercial prospects for Bapineuzumab**

- The top-line Phase II data on Bapineuzumab were better than our expectations given what look to be robust efficacy results in the ApoE4 non-carrier group.
- Increased confidence in the development prospects and commercial potential for the drug lead us to upgrade our risked valuation to \$31 (range \$27-\$32). Our models suggest unrisked upside to approximately \$42, based on a \$4.5bn peak revenue potential in AD [Alzheimer’s Disease].

\* \* \*

**Encouraging efficacy, consistent safety**

\* \* \*

Full data provision at ICAD will allow us to answer several more pertinent questions, chief among which are the following:

- What is the nature and trend of response across dose strengths?

54. On July 8, 2008, Cowen and Company published an analyst report entitled “Bapineuzumab Could Be A Breakthrough . . . But Several Hurdles Remain” and reported “***Bapineuzumab Phase II Results Exceeded Expectations.***”

55. On July 24, 2008, Stanford Group Company published an analyst report entitled “ELN: More questions to be answered at ICAD,” which stated in part:

- Bapineuzumab Phase 3 US studies on track to complete patient enrollment in 2008. Launched in Dec 2007, these two large 18-month trials (n=800; n=1,250) are enrolling well and the company expects to complete enrollment by the end of the year. Wyeth [] is six months behind in patient enrollment

(mid-09 complete) for two international Phase 3 studies of Bapineuzumab (over 2,000 patients).

\* \* \*

10 key questions we expect to be answered at ICAD:

\* \* \*

3. Is there dose response in efficacy endpoints?
4. Time effect of Bapineuzumab – time of effect onset, curve separation over time, and rate of decline?
56. On July 25, 2008, Natixis Bleichroeder published an analyst report which stated, in part:

The full bapineuzumab results will be shown during a 15-minute presentation at ICAD in Chicago on Tuesday, July 29.

\* \* \*

Key items we are looking for that would allow the stock to continue to work include:  
... **Early** and continuing separation of the curves over time – this will dictate the potential filing prior to the end of the 18-month endpoint, after a possible interim efficacy look .... A clear dose response ....

57. On July 25, 2008, Cowen and Company published an analyst report entitled “Raising Tysabri Outlook Post Solid Q2 Results, But It’s All About Bap.” The report stated in part:

Elan’s Q2 revenues came through ahead of our and the Street’s expectations, driven by better Tysabri trends. .... But **bapineuzumab is the stock-moving issue** ....

58. On July 28, 2008, Cowen and Company published an analyst report entitled “What To Look For In Tomorrow’s Bapineuzumab Phase II Data Presentation,” which stated in part:

The Phase II data for ELN/WYE’s bapineuzumab (Mab for Alzheimer’s) will be presented tomorrow afternoon at the International Conference on Alzheimer’s Disease (ICAD).

\* \* \*

1. **The relative efficacy curves:** The most important indicators of bapineuzumab's efficacy signal will be graphs of drug-placebo differences in change from baseline scores on cognitive measures (ADAS-cog and/or NTB) in combination with the global measure (CDR-sb). Early and sustained cognitive improvement – at least relative to the placebo decline (absolute improvement relative to baseline would be a bonus) is key to supporting a signal for bapineuzumab efficacy.

\* \* \*

Elan and Wyeth released brief top-line results from the bapineuzumab Phase II trial on June 17th. . . . Assuming a 6.5 point decline on the ADAS-cog score for the placebo group over 18 months, a 57-63% relative effect size for the bapineuzumab group translates to a 3.7-4.1 point spread vs. placebo (i.e. a 2.4-2.8 point absolute decline at 18 months). . . .

### THE TRUTH BEGINS TO EMERGE

59. On July 29, 2008, Elan and Wyeth jointly issued a press release which disclosed the following:

Elan Corporation, plc and Wyeth today are presenting detailed results from the companies' 18-month Phase 2 study of bapineuzumab (AAB-001) in patients with mild to moderate Alzheimer's disease at the Alzheimer's Association's International Conference on Alzheimer's Disease 2008 in Chicago, Illinois. As previously announced, in the study, bapineuzumab appeared to have an acceptable safety profile and clinical activity in treating Alzheimer's disease. *Potential efficacy signals were seen at a range of doses without a clear dose response.* The study did not attain statistical significance on the pre-specified efficacy endpoints in the overall study population. Post-hoc analyses showed statistically significant and clinically meaningful benefits in important subgroups.

\* \* \*

### Phase 3 Program Implications

*The Phase 2 data reinforce the design of the ongoing Phase 3 studies* by ApoE4 carrier and non-carrier populations and the selected dose groups. The companies plan to continue all four ongoing Phase 3 studies. The ApoE4 carrier dose in the Phase 3 trials was selected to seek to minimize the risk of VE observed in the Phase 2 trial. The companies intend to obtain feedback from regulatory authorities in the coming months to finalize parameters for the Phase 3 program and discuss and reach agreement on requirements for registration.

60. That same day, July 29, 2008, on an Elan/Wyeth conference call, additional, negative, information was disclosed:

Tim Anderson – Sanford C. Bernstein & Company, Inc. – Analyst:

Thank you. The company press release doesn't mention bleeding episodes, yet a press interview with someone in clinical development at Wyeth says there were three or four bleeds, which seems like it could be important, given how the drug works. I'm hoping you could characterize those patients better in terms of two things, ApoE4 carrier status and also the dose of drug that they received.

Chris Burns – Elan Corporation, PLC – SVP, Global IR:

Thanks, Tim. Dr. Black, perhaps comment on that.

Ron Black – Wyeth Research – Assistant VP Neuroscience:

Sure. I think when we talk about bleeding in particular, we need to distinguish what we're talking about here in this population. So these are microbleeds and these typically occur in Alzheimer patients and are asymptomatic, and in all the patients after every dose we do a type of MRI scan called a T2 Star MRI scan, which is very sensitive in detecting these microbleeds. Now in other population studies of Alzheimer's disease patients in which T2 Star scans are done, reports of up to 20% in the population of Alzheimer's disease – the microbleeds have been reported in up to 20% of Alzheimer's patients. In this case, we saw some of these microbleeds in patients with vasogenic edema. There were three of the patients out of the 12 with vasogenic edema who had these tiny little areas of microbleeding which you can only detect on this specific MRI sequence, and those patients – they didn't appear to be of any clinical consequence.

\* \* \*

Catherine Arnold – Credit Suisse – Analyst

Thanks for the follow-up. I wanted to ask you about the MMSE. Obviously you did point out the difference in the non-carrier group in terms of placebo and bapi. But I was wondering what happened to MMSE particularly in that group. And if you have any other comments for the trial overall, we didn't get to see that. Thanks.

Chris Burns – Elan Corporation, PLC – SVP, Global IR

Thanks. I think Allison, can you comment on that to some degree, or Dr. Gilman I think had some thoughts on that.

Sid Gilman – University of Michigan – Chair of Bapineuzumab Safety Monitoring Committee

We did evaluate MMSE throughout the trial. We didn't see a significant signal through the 78 weeks with MMSE, but MMSE is not a particularly great test vehicle for pharmaceutical evaluation. It's good to evaluate the level of dementia

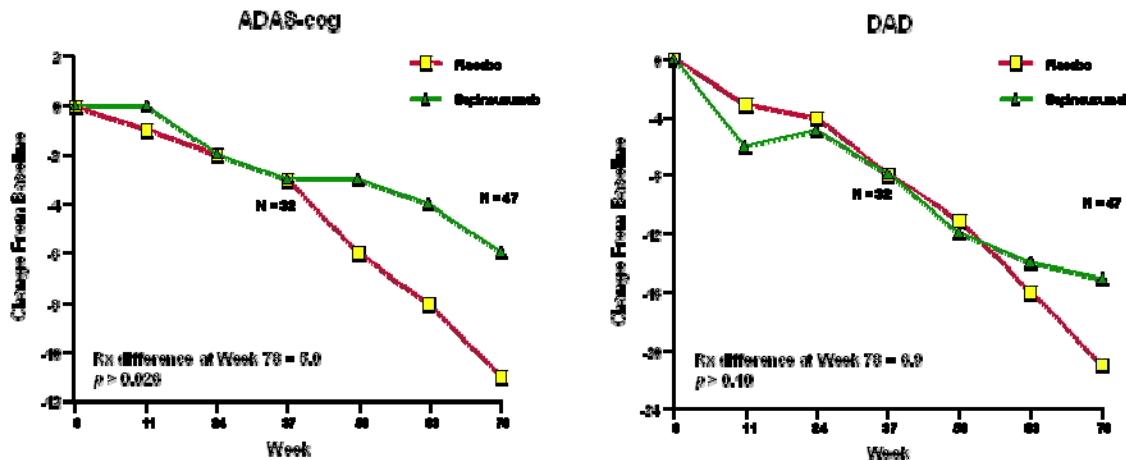
initially, but not to follow patients because of learning that can take place with it. There were signals but they were not particularly strong signals.

61. Along with the conference call, defendants presented a series of slides to investors that included the following disclosure of adverse events identified in the Phase 2 study:

- [Adverse Events] occurring  $\geq$  2 times as often as placebo rate and seen in  $>5\%$  of bapineuzumab patients

Back pain	12.1% vs 5.5%	Weight loss	6.5% vs 1.8%
Anxiety	11.3% vs 3.6%	Paranoia	6.5% vs 0.9%
Vomiting	9.7% vs 3.6%	Skin laceration	5.6% vs 2.7%
VE (vasogenic edema)	9.7% vs 0%	Gait disturbance	5.6% vs 1.8%
Hypertension	8.1% vs 3.6%	Muscle spasms	5.6% vs 0.9%

62. The slides also included the following charts showing bapineuzumab's performance compared to placebo over time using the two principle tests, ADAs-cog and DAD:



63. Between the presentation at the Chicago conference, the press release, and the conference call presentation, investors learned for the first time that:

(a) The Phase 2 Study showed no dose response, *i.e.*, taking higher doses of bapineuzumab did not correlate with greater improvement in symptoms. Normally, if a drug like bapineuzumab is effective, its effectiveness will increase as more is administered. The absence of a

dose response suggested that any improvement seen on bapineuzumab compared to placebo was random;

(b) Among ApoE4 non-carriers in the Phase 2 Study, the group in which some evidence of bapineuzumab's efficacy was purportedly found, the patients taking placebo showed a larger than expected cognitive decline. Specifically, the ADAS-cog scores of this group of patients (21 in all) dropped 11 points over the 78-week period of the trial. This was considered quite a dramatic decline by other scientists and physicians working in Alzheimer's disease clinical trials. On average, they would have expected an ADAS-cog decline of six to nine points among those taking placebo. To the extent the placebo group deteriorated more rapidly than average patients, it exaggerated the efficacy results of bapineuzumab in the study;

(c) In order to manufacture bapineuzumab's statistically significant outperformance of placebo in the Phase 2 Study, defendants changed the statistical model *post hoc* from linear to curvilinear. The original trial protocol called for linear modeling. Had defendants not changed to a curvilinear model without informing investors, they could not have claimed that bapineuzumab outperformed placebo by a statistically significant margin, even in the ApoE4 non-carrier group;

(d) Investors expected bapineuzumab to outperform placebo early in the trial because in a Phase I trial, it was reported that bapineuzumab began outperforming placebo at 16 weeks. Measured using the two primary tests the Phase 2 Study was designed to rely upon, bapineuzumab performed no better than placebo until well into the trial. Using the first such test, the DAD, patients taking bapineuzumab showed no improvement over placebo until 63 weeks into the 78-week study. Similarly, using the other, the ADAS-cog, patients taking bapineuzumab showed no improvement over placebo until 50 weeks into the 78-week study;

(e) Using the MMSE, which was a tertiary test, but which defendants characterized as a “key measure of cognitive function,” there was no significant signal that bapineuzumab worked better than placebo in the Phase 2 Study. The MMSE was the only test under which bapineuzumab was reported to have performed significantly better than placebo in Elan’s Phase 1 study;

(f) Nearly 10% of patients taking bapineuzumab in the Phase 2 Study (12 patients) developed a potentially dangerous accumulation of fluid in the brain known as vasogenic edema versus zero patients in the placebo group. Three of the bapineuzumab patients so affected also developed “micro bleeds” in their brains;

(g) Three deaths were reported in the group taking bapineuzumab compared to none in the placebo group. One of the deaths was caused in part by an aortic dissection (a tear in the wall of this major artery) which has the potential to be related to drugs such as bapineuzumab;

(h) There were nine additional adverse effects that occurred two or more times as often in patients taking bapineuzumab and in more than 5% of such patients, including back pain, anxiety, vomiting, hypertension, weight loss, paranoia, skin laceration, gait disturbance, and muscle spasms; and

(i) Bapineuzumab not only failed to show a statistically significant benefit compared to placebo per the original trial protocol, but failed to do so by a large margin.

64. When the complete Phase 2 Study results were finally disclosed, the price of Elan’s ADRs plunged 42% in one day as artificial inflation came out of the stock price. The adverse results of the Phase 2 Study meant that the Phase 3 trials would likely have to run their full 18-month courses before FDA approval would be possible. If the results of the Phase 2 Study had been as strong and spectacular as defendants claimed, there was a chance that Elan could have filed

for FDA approval based upon those results and an interim appraisal of the Phase 3 data. With disappointing results from the Phase 2 Study, this became highly unlikely. Thus, even if eventually approved by the FDA, any sales of bapineuzumab would not begin for many months, if not years, further into the future. This reduced the then-present value of bapineuzumab. Finally, the fully disclosed Phase 2 Study data suggested that bapineuzumab was unlikely to be greatly superior to Alzheimer's drugs already on the market, also limiting its commercial potential.

65. On July 30, 2008, Adam Feuerstein published an article on *TheStreet.com* entitled "Elan-Wyeth Alzheimer's Data Spook Bulls," which stated in part:

... Tuesday afternoon, *we finally got to see the actual data from the bapineuzumab study and it was wildly inconsistent.*

Let me give you one example: There was absolutely no dose response with bapineuzumab in this trial. Typically, you like to see increasingly higher doses of a drug correspond with improved efficacy. Instead, *what we saw from the bapineuzumab study just looked like so much randomness*, which in clinical trials is definitely not a good thing.

The lowest doses of the drug worked better on some measures of cognition and function, while higher doses worked better on others. Sometimes, doses in the middle produced worse results than placebo.

\* \* \*

The ApoE4 non-carrier group of patients was Elan and Wyeth's best shot at making a convincing case for bapineuzumab, but once again, *the details in the data Tuesday – stuff not available [to investors] in June – tripped them up.*

\* \* \*

When you look at the actual performance curves of the study, bapineuzumab-treated patients reported a 5-point improvement over placebo on the ADAS-cog test, a measure of cognition and a co-primary endpoint of the study.

However, for nearly a year into the 18-month trial, the bapineuzumab and placebo patients were both losing cognition at the same rate. The benefit seen for bapineuzumab patients only came about because placebo patients suffered a steep loss of cognition at the very end of the study.

\* \* \*

. . . [T]here is no good explanation for why bapineuzumab would take so long to be effective compared to placebo. The fact that the two ADAS-cog curves (bapineuzumab and placebo) were essentially identical for much of the first year of the study is a problem because most Elan “believers” thought the curves would separate early in bapineuzumab’s favor and remain that way for the entire length of the study.

\* \* \*

The loss of cognition by placebo patients totaled 11 points on the ADAS-cog scale at 18 months, far worse than is typically seen in other Alzheimer’s studies of this duration.

For instance, the placebo patients in the large phase III study of Myriad Genetics’ [MYGN – commentary – Cramer’s Take] Flurizan reported a 7-point loss of cognition on the ADAS-cog scale. These data, from a study much larger than Elan and Wyeth’s phase II, were also presented Tuesday at the conference.

The concern here is that the improvement in cognitive function seen in the ApoE4 non-carriers is not a result of anything that bapineuzumab is doing, but is instead caused by poor-performing placebo patients from a small subset analysis.

\* \* \*

Twelve patients in the study treated with bapineuzumab developed a potentially dangerous accumulation of fluid in the brain known as vasogenic edema. All of these cases resolved favorably however, and six of the patients were eventually able to continue treatment with bapineuzumab.

\* \* \*

There is another side to this safety story, however. Researchers were only able to detect the vasogenic edema by subjecting patients to numerous (and expensive) MRI scans. In the real world, Alzheimer’s patients will never be monitored this closely, so what happens if vasogenic edema goes undiagnosed and untreated in bapineuzumab patients?

Other safety issues: Several instances of bapineuzumab patients experiencing “micro-bleeds” in their brains, plus higher rates of seizures and psychiatric events.

66. On July 30, 2008, Caris & Company published an analyst report which stated in part:

Reality Check for Phase II Bappy Data . . . Investors and analysts finally got to see real data behind the Phase II bapineuzumab study conducted by Elan and partner, Wyeth (3\*/Average) at the International Conference on Alzheimer’s Disease (ICAD) meeting yesterday. . . . **[E]nough information was revealed to suggest that the**

***Phase II results could be completely invalid.*** In particular, no dose response, a placebo arm that behaved much worse than expected, and a contrived statistical methodology are the major criticisms of the data, in our view, which lead to our conclusion that the results previously released may not be valid after all. . . . [T]he statistical significance seen in the non carrier group using the ADAS-Cog scale was achieved against a placebo group that had an 11 point score decline. Based on our analysis, typical placebo groups would have declines in the 6-7 point range, which actually was the decline seen in the bapineuzumab-treated non-carrier patients. . . . Safety issues remain. The company reported 12 cases of vasogenic edema, with two in the treated APO-E4 non-carrier group. In addition, 3-4 incidences of micro-bleeds and 3 deaths occurred in bapineuzumab-treated patients . . . .

67. On July 30, 2008, Cowen and Company published an analyst report which stated in part:

***The presentation of the detailed bapineuzumab Phase II data yesterday at the ICAD meetings raised unexpected questions about the robustness of bapineuzumab's apparent efficacy – and about the chances for success in Phase III. . . .*** [T]he variability of the data, the lack of a dose-response, and the unusually sharp ADAS-cog decline in the placebo group all erode the strength of the efficacy signal. . . . ***With lower conviction in Phase III success for bapineuzumab and at least two years to wait for confirmation, we have trimmed our estimated bapineuzumab value by \$4-5B, or \$10 per ELN share,*** reflecting a higher discount rate.

\* \* \*

Elan was clipped . . . in after hours trading: we believe the raised risk profile of bapineuzumab reasonably trims \$4-5B (\$10/share) from the fair valuation. An early BLA filing and early visibility on Phase III now is unlikely.

68. Also on July 30, 2008, Canaccord Adams published an analyst report entitled “Bapineuzumab Disappoints,” which stated in part:

Yesterday, Elan and development partner Wyeth reported less-than-spectacular Phase 2 data from their lead Alzheimer’s disease drug bapineuzumab at the International Conference on Alzheimer’s Disease (ICAD) in Chicago.

Could I please get some more *post hoc* with my *post hoc* analysis?

\* \* \*

. . . In a *post hoc* analysis, in addition to subdividing the treated population into ApoE4 carriers and non-carriers, the companies used a modified intent-to-treat (MITT) analysis that assumed non-linearity in the data. While a *post hoc*

modification to the analysis such as this could reveal interesting facets of the clinical data, we cannot believe that it could be conclusively supportive of the efficacy of bapineuzumab in Alzheimer's disease.

\* \* \*

Of particular concern for us from the data presented was ***the obvious lack of a dose response across patient groups***. Although the companies attempted to explain the differences across the doses, we believe that the varying clinical responses on different endpoints are concerning. . . .

69. On July 30, 2008, Stanford Group Company also published an analyst report which stated in part:

Bapineuzumab Phase 2 data fails to meet high expectations . . . .

- Key issues that compounded the Phase 2 efficacy data: 1) the placebo arm performs worse in the ApoE non-carrier (ADAS-cog=-11 at 18 month vs. -7 or -8 points on average); 2) unexpected non-linear decline in placebo arm; 3) lack of dose-response.
- ***Safety signals seen also increase risks of Phase 3 studies***. 3 deaths occurred in the Bapi treatment arm (vs. 0 in placebo), adverse events seen double in Bapi treatment arm than placebo include back pain, anxiety, vomiting, vasogenic edema, hypertension.
- The underwhelming data makes accelerated FDA filing on interim analysis unlikely. . . .
- . . . We lowered our estimate for likelihood of Phase 3 success from prior 75% to 50% and our price target from \$28/sh to \$25/share.

70. On July 31, 2008, Credit Suisse published an analyst report which stated, in part:

. . . like the market, we remain disappointed in the lack of dose response in this data and the confusion surrounding the analysis conducted.

\* \* \*

- The move transition from a linear analysis to a non linear analysis for the Post Hoc analysis weakens findings

Credit Suisse:- We agree that this transition was not communicated well to the market. . . .

71. On July 31, 2008, NCB Stockbrokers Ltd. published an analyst report entitled “Update to Bapineuzumab Valuation; Target Price Reduced to \$22.40,” which stated in part:

Efficacy: It has been known since the release of the top line results in June that the ApoE4 non-carrier group demonstrated statistically significant benefits. The additional detail provided at ICAD showed an ADAS-cog difference of +5 points (versus placebo), however this result was on the basis of comparison with an 11 point decline in the placebo group (versus a 6 point decline in the treated group). An 11 point decline is considered to be at the upper end of expected range for non-treated (placebo) patients and somewhat undermines the veracity of the statistically significant results.

\* \* \*

Dosage – Mixed signals: Within the non-carrier group, the 0.5mg/kg dose showed the largest improvement across all four efficacy scales, however there was no clear dose response evident.

In light of these details which undermine the case for disease modifying efficacy, point to more pronounced safety questions, and push out any likely commercialization date we have reduced our NPV for bapineuzumab from \$8.1bn to \$3.4bn.

72. On August 1, 2008, *TheStreet.com* published an article entitled “Feuerstein’s Biotech-Stock Mailbag: Elan,” which stated in part:

Is there any compelling reason to own Elan now? Bapineuzumab looks like a crapshoot at best, and news flow around the program goes dark as the phase III studies enroll patients and we wait two years for data. Many bulls were hoping for an early or accelerated approval filing. Please, ***the bapineuzumab data are so weak, that rosy scenario is now pure fantasy.***

\* \* \*

More on Elan from Stanley W. [one of Mr. Feuerstein’s readers] who wrote:

***I don’t understand how Kelly Martin could be so bullish on bapineuzumab based on this data. Did he mislead us all??***

Kelly Martin, Elan’s CEO, has a BIG credibility problem with Wall Street. Without naming names, let’s just say that I saw a couple of Elan’s largest institutional shareholders at the ICAD conference Tuesday night, and they looked like they wanted to take Martin into an alley and, well, you get the idea.

In an interview with *CNBC* Wednesday morning, Martin tried to blame Elan's selloff on too-high expectations and investors who want simple answers to complex questions.

That's laughable. ***It was Martin, himself, who set those high expectations for bapineuzumab***, and the data aren't difficult at all to understand.

73. On August 1, 2008, the *Irish Independent* stated:

Over EUR3bn has been slashed off Elan's market capitalisation since Tuesday, when the drugmaker announced disappointing data on its Alzheimer's Disease treatment Bapineuzumab . . . .

74. On August 4, 2008, Cowen and Company published an analyst report entitled "ELN Has Longer-Term Value, But Debt Overhang Likely Keeps A Lid On Shares," which stated in part:

(3) The disappointing observation was that bapineuzumab's efficacy signal in the ApoE4 non-carriers was weakened enough by the high variability across doses and the unusually sharp cognitive decline in the placebo group that ***the 4,100-patient Phase III trial now is more of a proof-of-concept trial than a confirmatory efficacy and safety trial***. . . .

. . . We now estimate bapineuzumab's 2015 global sales at \$6.0B, based on 28% penetration of the estimated treated ApoE4 non-carrier AD patients with mild/moderate disease in the U.S. and 20% penetration of the similar patient population outside the US (versus 25-35% previously). We have increased the discount rate we apply in valuating the bapineuzumab revenue stream to Elan (Wyeth and Elan split the bapineuzumab costs and potential revenues 50/50) from 20% to 35%, reflecting the higher risk profile of the ongoing Phase III program. The result: ***we now estimate the present value of the bapineuzumab program to Elan at \$2.6B, or \$5-6 per share, down from \$8.4B, or \$17-18 per share, prior to the presentation of the Phase II data.***

75. Even after the disclosure of the materially adverse results of the Phase 2 Study, the price of Elan securities continued to trade at artificially inflated prices due to defendants' false and misleading statement that "the Phase 2 data reinforces the design of the ongoing Phase 3 studies." In fact, the Phase 2 Study data caused a significant delay in those studies.

76. The Phase 3 trials of bapineuzumab consisted of two trials to be conducted by Elan in the United States and two trials to be conducted by Wyeth in Europe. Enrollment began in December 2007. On October 22, 2008, however, Wyeth finally disclosed in a conference call that

European regulators had asked that the European trials of bapineuzumab be delayed following the disappointing results of the Phase 2 Study, as follows:

David Risinger – Merrill Lynch – Analyst:

Yes. Thanks very much. You had mentioned that with respect to bapineuzumab in Europe, you're engaging in meetings with Regulatory Authorities before they permit enrollment and/or permit continued dosing. Can you explain what changed to slow enrollment relative to your original expectation several months ago, and then just a quick second question that I'd like to slide in. Can you just explain the FX benefit to EPS? Thank you.

Justin Victoria – Wyeth – VP, IR:

All right, let me ask Joe to start on the bapineuzumab and then Greg will comment on the FX.

Joe Mahady – Wyeth – SVP, President, Global Pharmaceutical:

David, very short, bapineuzumab in Europe was always projected to be running behind in terms of the US study start date and June was when we just begun to enroll certain centers in certain countries. *With the information that broke with the Phase II data and publicity around it, in the ensuing weeks and months we began to get requests from individual countries to review the full Phase II data*, to review the Phase III protocols, any protocol amendments that had been implemented and that has been going on for the past few weeks. As a consequence, in places where and in many places we had yet to begin enrollment they had asked that that enrollment not begin until they completed that review and a couple of countries where enrollment had just begin, they asked us to hold until they finish this review. Those meetings and those submissions are ongoing as we speak and hope to have better understanding of where we are but I think your insight is correct. We really are a little behind where we would like to be in getting the full European program up and running.

77. On this news, Elan's ADRs declined again, from \$9.06 per share to \$7.82 per share in one day, dropping more than 13% as artificial inflation in the price of the Company's securities caused by defendants' false statements and omissions continued to dissipate.

#### **POST-CLASS PERIOD EVENTS**

78. Immediately following the disclosure of the delay in the Phase 3 studies, Cowen and Company published an October 23, 2008 analyst report which stated, in part:

Wyeth management disclosed yesterday that patient enrollment for the international segment of the bapineuzumab (Alzheimer's) Phase 3 clinical trials is running behind targets. ELN shares were hit by 13%+ on the disclosure, essentially removing bapineuzumab from the valuation.

\* \* \*

- Wyeth: Bapineuzumab Ex-U.S. Phase 3 Enrollment Lagging. In a few countries where the bapineuzumab Phase 3 enrollment has not started or is very early, regulators have requested a review of the Phase 2 data. While no indication was given on the extent of the enrollment delay, we have delayed our enrollment completion target for the international trials by 3-6 months, to late '09.

79. On October 23, 2008, Canaccord Adams also published an analyst report which stated, in part:

The delay in enrollment in the European arms of the current phase 3 trials has unsettled the stock, especially as it appears to be driven by the participating countries' requests for additional information, especially safety data, and wish to have further time to review the protocols.

80. On December 11, 2008, *TheStreet.com* published an article entitled "Elan's Martin Named Worst Biotech CEO of '08," explaining:

*Martin . . . and his management team promised investors the sky and more when it came to Elan's experimental Alzheimer's disease drug bapineuzumab.*

*Unfortunately for Martin, the high expectations he set for the drug never materialized. As a result, Elan's share price fell through the floor, the company's investors lost a fortune and Martin's reputation and credibility were shattered.*

*Elan's stock price is down about 70% for the year and 80% from its high in early July, right before the big bapineuzumab setback sent shares plunging, never to recover.*

#### **DEFENDANTS' SCIENTER**

81. During the Class Period, defendants had knowledge of the misleading nature of the statements they made and acted in reckless disregard of the true information known and available to them at the time. In so doing, defendants participated in a scheme to defraud and committed

acts, practices, and participated in a course of business that operated as a fraud or deceit on purchasers of Elan ADRs during the Class Period.

82. Throughout the Class Period, defendants conceded that they were fully aware of the interim review and final Phase 2 Study results. Defendants specifically stated both that they would and that they did review the interim results of the Phase 2 Study in the spring of 2007. *See ¶¶33-35, 37 and 44.* After the Phase 2 Study was completed in April 2008, defendants again assured analysts and investors that they had reviewed and were familiar with the study results. *See ¶48.* Throughout the Class Period, defendants responded to inquiries from investors and analysts regarding the bapineuzumab Phase 2 Study and at no time did they ever claim that they were unaware of the study results. *See, e.g., ¶44.*

83. A positive perception of bapineuzumab was critically important to Elan because sales of its biggest selling drug, Tysabri, were still crippled by reports of side effects while sales of a number of other Elan drugs were plummeting due to generic competition. Specifically, the FDA approved a generic version of Maxipine, Elan's treatment for pneumonia, in June of 2007, precipitating a \$52.2 million write-off by Elan. More importantly, bapineuzumab had the potential to be the "biggest drug of all time" and, according to analysts, generate upwards of \$4-\$5 billion in revenue per year. In comparison, Elan's total revenue in 2007 was \$759 million. As the *Associated Press* stated prior to the end of the Class Period, "[w]ith an effective treatment for Alzheimer's being one of the holy grails of the pharmaceutical world, the rewards for Elan for bringing a successful drug to market would be incalculable." Accordingly, financial analysts reported that "bapineuzumab is the stock-moving issue" for Elan and, more succinctly, "it's all about bap."

84. Elan's Form 20-F annual report filed with the SEC on February 28, 2008, stated: "Our future success depends upon the continued successful commercialization of Tysabri and the successful development and commercialization of additional products. . . . We have committed significant resources to the development and the commercialization of Tysabri and to the other potential products in our development pipeline (in particular, AAB-001 [bapineuzumab]) . . . . ***If our Phase 2 and 3 clinical trials for AAB-001 [bapineuzumab] are not successfully completed, we will be materially and adversely affected.***"

85. Defendants were further motivated to conceal the adverse results of the Phase 2 Study to enroll the Phase 3 trials which Elan needed to conduct before it could receive FDA approval for bapineuzumab. Indeed, Elan's President, Carlos Paya, said in February 2009 that the Company's "number one focus" was to finish the Phase 3 studies "as quickly as we can." Adverse Phase 2 Study results would, and did, cause regulators to delay two of the Phase 3 trials. Moreover, publicity calling into question the safety or efficacy of bapineuzumab was likely to slow enrollment in the Phase 3 studies. Doctors are more likely to encourage their patients to participate in a trial of a drug that is considered safe and efficacious, and patients are more likely to accept such a recommendation. Accordingly, the longer defendants could maintain the illusion of strong and spectacular Phase 2 Study results, the faster the Phase 3 studies could enroll and, defendants hoped, generate positive results. Conversely, defendants knew from their experience in the pharmaceutical industry that once the disappointing Phase 2 Study results were publicly disclosed, Phase 3 enrollment would dramatically slow down. That is exactly what happened. On April 22, 2009, Elan acknowledged that one of the Phase 3 trials in the U.S. was only 60% enrolled and would not be fully enrolled until the end of 2009. By comparison, during the Class Period and before the truth

about the Phase 2 Study was revealed, defendants had stated that they expected both domestic trials would be fully enrolled by the end of 2008.

86. On October 13, 2008, at Natixis Bleichroeder Hidden Gems Conference, defendant Martin made the following statements:

[Martin]: Phase III, just to review, is a 4,000-patient trial. There's four different trials. They're all pivotal. There's two in North America, there's two rest of world.

\* \* \*

... we're going to be very careful not to cause unnecessary distractions for the people doing the trial.

\* \* \*

Just suffice it to say that both companies are anxious to get the enrollment completed. We're most interested in getting outcomes for the Phase IIIs. And as much information as we can provide broad direction, we will do that. I'm not sure we're going to give super-specific information, because at the end of the day, I think that harms the ability to execute the trial.

#### **LOSS CAUSATION/ECONOMIC LOSS**

87. During the Class Period, as detailed herein, defendants engaged in a scheme to deceive investors and the market and a course of conduct that artificially inflated and maintained Elan's ADR price and operated as a fraud or deceit on Class Period purchasers of Elan ADRs by misrepresenting and omitting the materially adverse results of the Phase 2 Study. When defendants' prior misrepresentations and omissions came to light and the adverse Phase 2 Study results were finally disclosed, the price of Elan's ADRs fell precipitously as the prior artificial inflation came out of the price. As a result of their purchases of Elan ADRs during the Class Period, plaintiffs and other members of the Class, suffered economic loss, *i.e.*, damages, under the federal securities laws.

88. As a direct result of the July 29, 2008 and October 22, 2008 disclosures, the price of Elan ADRs dropped immediately. After the July 29, 2008 disclosures, the price of Elan's ADRs

dropped 42% in one day, falling from a July 29 close of \$33.75 per share to a July 30 close of \$19.63. Volume increased dramatically from 18 million ADRs traded on July 29 to 82 million traded on July 30 as the market reacted to the revelations about the Phase 2 Study of bapineuzumab. After the July 29, 2008 disclosures, analysts noted that the price of Elan securities was “clipped” in after hours trading, stating “we believe the raised risk profile of bapineuzumab reasonably trims \$4-5B (\$10/share) from the fair valuation.”

89. On July 30, 2008, the *Dow Jones* news service reported:

Elan Corp. shares plunged Wednesday as a midstage study on their experimental Alzheimer’s disease drug appeared to present more questions than answers, with concerns centered around a potential safety complication and patients’ response to different dosages.

The findings of the 240-patient study, which were released at the International Conference on Alzheimer’s Disease on Tuesday, led Wall Street to start discounting the potential of the drug, called bapineuzumab.

\* \* \*

Shares of Elan, based in Dublin, plunged 40% to \$20.25.

The sell-offs highlighted investor uncertainty regarding bapineuzumab’s potential, following a period in which *the value of both companies improved behind mounting expectations for the drug. Those expectations were fueled by partial data released June 17 that suggested benefits for a sub-group of Alzheimer’s patients. However, the slide in Wyeth and Elan shares on Wednesday more than wiped out gains posted following the partial-data release.*

A successful Alzheimer’s drug could be a blockbuster, given the brain-harming disease affects more than 5 million Americans and the tally is likely to surge as baby boomers age. Also, there are no approved drugs today that alter the progression of the disease, kicking the door wide open for a better treatment.

90. Even defendant Martin conceded in the Company’s October 23, 2008 earnings press release that “[t]he brief overview presentation of the Phase II data . . . at the International Conference on Alzheimer’s Disease (ICAD) . . . contributed to increased volatility in our equity value and a change in the risk perception of Elan within the marketplace.”

91. After the October 22, 2008 disclosure, the price of Elan's ADRs fell from a closing price of \$9.06 on October 22 to \$7.82 on October 23, a decline of over 13%. The price of Elan stock on the Dublin Stock Exchange similarly fell from €6.20 to €5.64. Analysts attributed this decline to the disclosures during Wyeth's conference call, stating "ELN shares were hit by 13%+ on the disclosure [of the delay in the Phase 3 studies]."

92. These price drops removed the inflation from the price of Elan's ADRs, causing real economic loss to investors who had purchased ADRs during the Class Period. They were a direct result of the nature and extent of defendants' prior false statements and omissions being revealed to investors and the market. The timing and magnitude of these declines negate any inference that the loss suffered by plaintiffs and other Class members was caused by changed market conditions, macroeconomic or industry factors or Company-specific facts unrelated to the defendants' fraudulent conduct. After both the July 29, 2008 and October 22, 2008 disclosures, the Dow Jones Industrial Average actually increased and no analysts attributed Elan's price declines on those days to any microeconomic or industry factors. The economic loss, *i.e.*, damages, suffered by plaintiffs and other members of the Class, was a direct result of defendants' fraudulent scheme to artificially inflate the price of Elan's securities, including its ADRs, and maintain the price at artificially inflated levels and the subsequent significant decline in the value of Elan securities when defendants' prior misrepresentations and omissions were revealed.

### **NO SAFE HARBOR**

93. Elan's verbal "Safe Harbor" warnings accompanying its oral forward-looking statements ("FLS") issued during the Class Period were ineffective to shield those statements from liability.

94. The defendants are also liable for any false FLS pleaded because, at the time each FLS was made, the speaker knew the FLS was false and the FLS was authorized and/or approved

by an executive officer of Elan who knew that the FLS was false. None of the historic or present tense statements made by defendants were assumptions underlying or relating to any plan, projection, or statement of future economic performance, as they were not stated to be such assumptions underlying or relating to any projection or statement of future economic performance when made, nor were any of the projections or forecasts made by defendants expressly related to or stated to be dependent on those historic or present tense statements when made.

### **APPLICABILITY OF PRESUMPTION OF RELIANCE: FRAUD ON THE MARKET**

95. Plaintiffs will rely upon the presumption of reliance established by the fraud-on-the-market doctrine in that, among other things:

- (a) Defendants made public misrepresentations or failed to disclose material facts during the Class Period;
- (b) The omissions and misrepresentations were material;
- (c) The Company's ADRs traded in efficient markets;
- (d) The misrepresentations alleged would tend to induce a reasonable investor to misjudge the value of the Company's ADRs; and
- (e) Plaintiffs and other members of the Class purchased Elan ADRs between the time defendants misrepresented or failed to disclose material facts and the time the true facts were disclosed, without knowledge of the misrepresented or omitted facts.

96. At all relevant times, the markets for Elan ADRs were efficient for the following reasons, among others:

- (a) As a regulated issuer, Elan filed periodic public reports with the SEC;
- (b) Elan regularly communicated with public investors via established market communication mechanisms, including through regular disseminations of press releases on the major

news wire services and through other wide-ranging public disclosures, such as communications with the financial press, securities analysts and other similar reporting services; and

(c) Elan ADRs were actively traded in an efficient market, the NYSE, under the symbol ELN.

### **CLASS ACTION ALLEGATIONS**

97. Plaintiffs bring this action as a class action pursuant to Rule 23 of the Federal Rules of Civil Procedure on behalf of all persons who purchased Elan ADRs listed and trading on the NYSE during the Class Period (the “Class”). Excluded from the Class are defendants, directors and officers of Elan and their families and affiliates.

98. The members of the Class are so numerous that joinder of all members is impracticable. The disposition of their claims in a class action will provide substantial benefits to the parties and the Court. During the Class Period Elan had millions of ADRs and outstanding, owned by thousands of persons.

99. There is a well-defined community of interest in the questions of law and fact involved in this case. Questions of law and fact common to the members of the Class which predominate over questions which may affect individual Class members include:

- (a) Whether defendants violated the 1934 Act;
- (b) Whether defendants omitted and/or misrepresented material facts;
- (c) Whether defendants’ statements omitted material facts necessary in order to make the statements made, in light of the circumstances under which they were made, not misleading;
- (d) Whether defendants knew or recklessly disregarded that their statements were false and misleading;
- (e) Whether the prices of Elan ADRs were artificially inflated; and

(f) The extent of damage sustained by Class members and the appropriate measure of damages.

100. Plaintiffs' claims are typical of those of the Class because plaintiffs and the Class sustained damages from defendants' wrongful conduct.

101. Plaintiffs will adequately protect the interests of the Class and have retained counsel who are experienced in class action securities litigation. Plaintiffs have no interests which conflict with those of the Class.

102. A class action is superior to other available methods for the fair and efficient adjudication of this controversy.

## COUNT I

### **For Violation of §10(b) of the 1934 Act and Rule 10b-5 Against All Defendants**

103. Plaintiffs incorporate ¶¶1-102 by reference.

104. During the Class Period, defendants disseminated or approved the false statements specified above, which they knew or recklessly disregarded were misleading in that they contained misrepresentations and failed to disclose material facts necessary in order to make the statements made, in light of the circumstances under which they were made, not misleading.

105. Defendants violated §10(b) of the 1934 Act and Rule 10b-5 in that they:

(a) Employed devices, schemes, and artifices to defraud;

(b) Made untrue statements of material facts or omitted to state material facts necessary in order to make the statements made, in light of the circumstances under which they were made, not misleading; or

(c) Engaged in acts, practices, and a course of business that operated as a fraud or deceit upon plaintiffs and others similarly situated in connection with their purchases of Elan ADRs during the Class Period.

106. Plaintiffs and the Class have suffered damages in that, in reliance on the integrity of the market, they paid artificially inflated prices for Elan ADRs. Plaintiffs and the Class would not have purchased Elan ADRs at the prices they paid, or at all, if they had been aware that the market prices had been artificially and falsely inflated by defendants' misleading statements.

107. As a direct and proximate result of defendants' wrongful conduct, plaintiffs and the other members of the Class suffered damages in connection with their purchases of Elan ADRs during the Class Period.

## COUNT II

### **For Violation of §20(a) of the 1934 Act Against All Defendants**

108. Plaintiffs incorporate ¶¶1-107 by reference.

109. The Individual Defendants acted as controlling persons of Elan within the meaning of §20(a) of the 1934 Act. By virtue of their positions and their power to control public statements about Elan, the Individual Defendants had the power and ability to control the actions of Elan and its employees. Elan controlled the Individual Defendants and its other officers and employees. By reason of such conduct, defendants are liable pursuant to §20(a) of the 1934 Act.

## **PRAYER FOR RELIEF**

WHEREFORE, plaintiffs pray for judgment as follows:

- A. Declaring this action to be a proper class action pursuant to Fed. R. Civ. P. 23;
- B. Awarding plaintiffs and the members of the Class damages and interest;
- C. Awarding plaintiffs' reasonable costs, including attorneys' fees; and

D. Awarding such equitable/injunctive or other relief as the Court may deem just and proper.

**JURY DEMAND**

Plaintiffs demand a trial by jury.

DATED: March 25, 2011

SCOTT+SCOTT LLP  
BETH A. KASWAN  
JOSEPH P. GUGLIELMO  
THOMAS L. LAUGHLIN, IV



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Additional Counsel for Plaintiffs

**CERTIFICATE OF SERVICE**

I hereby certify that the foregoing Amended Consolidated Complaint for Violations of the Federal Securities Laws was served via regular U.S. Mail this 25<sup>th</sup> day of March, 2011, upon the following counsel of record:

Daniel Martin Segal  
Jaculin Aaron  
Shearman & Sterling LLP  
599 Lexington Avenue  
New York, NY 10022

*Counsel for Defendants*

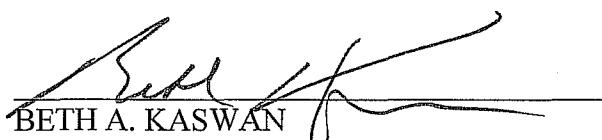
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## **EXHIBIT A**

**CERTIFICATION PURSUANT TO  
THE FEDERAL SECURITIES LAWS**

I, Luc Lemmerling, hereby certify as to the claims asserted under the federal securities laws that:

1. I am over the age of 18. I am familiar with the allegations in this matter, have reviewed the complaint and authorize Scott+Scott LLP to file a complaint and/or lead plaintiff papers on my behalf in this matter.

2. I did not purchase the securities that are the subject of this action at the direction of counsel or in order to participate in any action arising under the federal securities laws.

3. I am willing to serve as a lead plaintiff and representative party on behalf of the Class (as defined in the Complaint), including providing testimony at deposition and trial, if necessary. I fully understand the duties and responsibilities of the lead plaintiff under the Private Securities Litigation Reform Act, including the selection and retention of counsel and overseeing the prosecution of the action for the Class.

4. During the Class Period (as defined in the Complaint), I purchased and/or sold Elan American Depository Receipts ("ADRs") which traded on the New York Stock Exchange that are the subject of this action as set forth on the attached Schedule A.

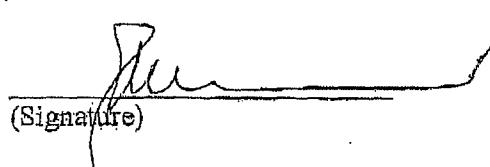
5. During the three-year period preceding the date of my signing this Certification, I sought to serve, or served as a representative party or lead plaintiff on behalf of a class in the following private action(s) arising under the Securities Act of 1933 (the "Securities Act") or the Securities Exchange Act of 1934 (the "Exchange Act"):

*In re Elan Corporation Securities Litigation, 1:08-cv-08761-AKH (S.D.N.Y.)*  
(Moved for Lead Plaintiff, but was not appointed)

6. I will not accept any payment for serving as a representative party on behalf of the Class beyond my pro rata share of any recovery, except such reasonable costs and expenses (including lost wages) directly relating to the representation of the Class, as ordered or approved by the court.

I declare under penalty of perjury that the foregoing is true and correct. Executed this  
15 th day of November, 2010.

Luc J. LEMMERLING  
(Print Name)

  
(Signature)

SCHEDULE A**LUC LEMMERLING**

Class Period Transactions in ELAN CORP PLC ADR

(Class Period: 5/21/2007 Through 10/21/2008)

<u>Trade Date</u>	<u>Action (Buy/Sell)</u>	<u>Quantity</u>	<u>Price Per Share</u>
5/24/2007	buy	1,000	\$18.73
7/2/2007	buy	3,500	\$22.53
7/2/2007	sell	-600	\$22.48
7/19/2007	sell	-2,000	\$22.00
7/19/2007	sell	-10,000	\$21.17
7/23/2007	buy	1,000	\$20.65
7/23/2007	buy	3,000	\$20.68
7/23/2007	buy	2,700	\$20.87
7/23/2007	buy	500	\$20.73
7/26/2007	buy	2,000	\$19.47
7/26/2007	buy	2,000	\$19.36
7/30/2007	buy	3,000	\$18.30
7/30/2007	buy	3,000	\$17.26
3/10/2008	sell	-300	\$19.11
3/11/2008	sell	-200	\$19.13
3/11/2008	sell	-100	\$19.03
3/11/2008	sell	-300	\$18.68
6/19/2008	sell	-3,000	\$29.30
7/6/2008	sell	-3,600	\$33.46
7/21/2008	buy	15,000	\$34.88
9/8/2008	sell	-13,000	\$12.73
10/10/2008	buy	1,500	\$8.15